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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/588,493

09/28/2006

Maximilian Fleischer

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8341

466 7590 03/16/2010

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EXAMINER

SNYDER, STUART

ART UNIT

PAPER NUMBER

1648

NOTIFICATION DATE

DELIVERY MODE

03/16/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/588,493 | <b>Applicant(s)</b><br>FLEISCHER ET AL. |  |
|                              | <b>Examiner</b><br>STUART W. SNYDER  | <b>Art Unit</b><br>1648                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 June 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Comment*

1. The Office Action Mailed 2/18/2020 is vacated.

### *Claim Objections*

2. Objection to claims 2 and 8 because of informalities is **withdrawn** in view of Applicants' amendment of the claims.

### *Drawings*

3. The drawings were received on 6/12/2009. These drawings are acceptable.
4. Objection to Figures 1 and 4 is **withdrawn** in view of Applicants' amendment of the specification filed 6/12/2009.

### *Claim Rejections - 35 USC § 112*

5. Rejection of claims 1-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in view of Applicants' amendment of the claims is **withdrawn** in view of amendment of the claims.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Rejection of claims 1, 4-9, and 18-20 under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter *et al.*, El Shami *et al.*, and Niwa *et al.* is **maintained**. Rationale for the rejection is detailed in the previous Office Action. Applicants traverse the rejection for the following reasons: 1) No single biosensor disclosed by Wohlstadter contains all the features of claim 1 of the instant application; 2) Wohlstadter does not disclose a counter-electrode in addition to the interdigital electrode on the same substrate; 3) the spacing of the interdigitated electrodes disclosed by Wohlstadter is different than is disclosed in the instant Application; 4) the surface upon which the first protein coat is layered disclosed by Wohlstadter is different from that of the instant Application; and 5) the second layer (an antibody) disclosed in the instant Application is not disclosed by Wohlstadter. Furthermore, Applicants allege that El Shami and Niwa do not remedy the shortcomings of Wohlstadter for the following reasons: 1) The problems to be solved by El Shami and Wohlstadter are different and so one of ordinary skill in the arts would not look to El Shami to modify Wohlstadter; 2) there is no description of electrochemical detection, electrodes, protein layer systems or redox reactive molecules in the combined teachings of Wohlstadter and El Shami which are claimed in claim 1 of the instant Application; 3) Niwa discloses only an interdigitated array usable for redox cycling, but not protein layer assemblies or antigen/antibody detection as required in claim 1 of the instant Application. With regard to rejection of claims 2-3 and 11-17, Applicants traverse the obviousness rejection for the following reason: Although Pettit

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teaches proteins of a first and second protein layers, an antigen, and the method of using the biosensor of claim 1, it does not cure the alleged deficiencies of Wohlstadter, El Shami and Niwa.

Applicants' arguments have been carefully considered and are not found persuasive. With regard to Wohlstadter: 1) It does not matter that Wohlstadter does not teach all of the features of the instantly claimed biosensor in one biosensor. If that were the case, the Examiner would have made an anticipation rejection not an obviousness-type rejection. The Examiner relied on the combined features of Wohlstadter, El Shami and Niwa to make the obviousness rejection. 2) Whether or not Wohlstadter teaches the same substrate as claimed in the instant Application is also immaterial because Niwa teaches silicon as substrate for the electrodes. Furthermore, silicon is one of a few options for electrode substrates making it an obvious substitution for the substrates disclosed by Wohlstadter. 3) Applicants' assertion that because the problems solved by El Shami and Wohlstadter were different, that a skilled artisan would have no reason to combine the two teachings. This is not convincing because scientists and skilled artisans look for any appropriate tool to solve scientific and technical problems whether or not the tools are in their current repertoire; scientists and technicians are constantly looking for new ways to solve problems and are not limited by techniques which they currently use. 4) Applicants' allegation that the combination of Wohlstadter and El Shami does not describe electrochemical detection, electrodes, protein layers or redox reactive molecules

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is moot because of the teaching of Niwa with regard to redox cycling and the teachings of Wohlstadter regarding electrochemical detection electrodes and protein layers taught by Wohlstadter. Furthermore, it is inherently obvious to substitute a two protein system including an antibody as the capture agent for a single layer comprising the capture antibody. This is evident in the use by Wohlstadter of a streptavidin-biotinylated antibody capture system as well as a single antibody layer as alternative capture systems.

6. Rejection of claims 2, 3, 10-17 under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter *et al.*, El Shami *et al.*, Niwa *et al.* and Pettit is **maintained**. Rationale for the rejection is detailed in the previous Office Action. Applicants argue that Pettit does not remedy the alleged deficiencies of the combination of Wohlstadter, El Shami and Niwa. Applicants further suggest that there would have been no reason to combine the cited literature.

With regard to Applicants' traversal of the obviousness rejection involving Pettit, Applicant does not dispute that Pettit teaches proteins of a first and second layers, types of antigens, nature of signal detection and the method of using the biosensor. Applicant simply states that Pettit does not remedy the alleged deficiencies of the combination of Wohlstadter, El Shami, and Niwa. However, the Examiner has successfully rebutted the allegations of Applicant with regard to the deficiencies of Wohlstadter, El Shami, and Niwa and thus Applicants' arguments are moot.

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In sum, the Examiner has demonstrated the suitability of the combination of Wohlstadter, El Shami, Niwa and Pettit in rendering the instantly claimed biosensor obvious and therefore maintains the obviousness rejection based on the combination of Wohlstadter, El Shami, Niwa and Pettit.

Finally, through a typographical error, claim 10 was omitted in the 103(a) rejection of claims 1, 4-9 and 18-20. El Shami clearly teaches that allergens may be antigens used in immunoassays (see Background section and throughout).

### ***Conclusion***

7. No claims are allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/  
Primary Examiner, Art Unit 1648

Stuart W Snyder  
Examiner  
Art Unit 1648

SWS